UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,309	07/02/2001	Robert B. Odell	P-3946C1C1	1739

7590 06/18/2002

Becton, Dickinson and Company
1 Becton Dr.
Franklin Lakes, NJ 07417-1880

EXAMINER
HUYNH, LOUIS K

ART UNIT	PAPER NUMBER
3721	

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,309	ODELL ET AL.	
	Examiner	Art Unit	
	Louis K. Huynh	3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

2. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

3. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,189,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter.

Priority

5. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) and 120 as follows:

> An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not disclose the container being sterilized after enclosed in a second container.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 20-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20, lines 6-7: "placing said array in a container and closing said container to form said syringe assemblies" is confusing because it is unclear as to how a closed

container containing an array of syringe barrel assemblies can form the syringe barrel assemblies.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1-18, 33-34 and 37-38 are rejected under 35 U.S.C. 102(a) as being anticipated by Lawecki et al. (US 5,687,542).

Lawecki et al. discloses a method of producing a container/syringe barrel including the steps of: forming a container/syringe barrel (126) in a forming device (18), transferring the container/syringe barrel to an enclosure (10) of class 100 environment (col.3, lines 5-10) without any cleaning or sterilization, cleaning the container/syringe barrel by directing a stream of filtered air toward the container/syringe barrel to keep contaminants from setting on the container/syringe barrel (col.4, lines 22-24), lubricating the container/syringe barrel (col.8, lines 19-25), supplying and lubricating tip caps and stoppers (col.8, lines 22-25), optional steps of filling the container/syringe barrel (col.8, lines 25-29) to form a prefilled syringe, placing the container/syringe barrel/prefilled syringe in a holder (68) (col.7, lines 17-21), enclosing the container/syringe/prefilled syringe barrel in a second container (128) (col.7 lines 25-28), and removing the container/syringe barrel/prefilled syringe from the enclosure (col.7, lines 35-43).

Regarding claims 3, 6, 10-11 and 16-17, Lawecki et al. discloses that the container (126) can be formed from either plastic (preferred embodiment) or glass

through a process that generates enough heat (i.e. heating a glass tube at one end to form a flange, heating the glass tube for shaping the other end to receive a cannula needle, heating the glass barrel to an annealing temperature, etc.) to render an article substantially free from contaminants (col.3, lines 38-43).

Regarding claims 4, 7, 15 and 18, the process disclosed by Lawecki et al. can be modified to include filling the container with a desired substance and assemble steps, i.e. lubricating the syringe barrel and stopper, applying tip cap, applying stopper, etc. (col.8, lines 19-29) to complete the assembly of a prefilled syringe (col.2, lines 31-38).

Regarding claims 8-9 and 13-14, Lawecki et al. discloses a HEPA filter (50) including an independent blower (col.4, lines 33-41) drawing the air from a class 100.000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment fully enveloping the syringe (col.4, lines 44-50) to keep contaminants from setting on the syringe (col.4, lines 22-24). Lawecki et al. further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (col.4, lines 51-54). Lawecki et al. also discloses an overhead fixture (114) including an ion bar anti-static assemblies (col.7, lines 9-10) for reducing static charge of the syringe.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 3 and 10-11 are alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

To the extent that applicants do not agree that the container is formed from glass, then Logothetis discloses a method for forming a glass syringe barrel (1) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (col.3, lines 57-62), see figs.1 & 2; the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (col.5, lines 8-14), see fig.5; the syringe barrel assembly is then heated to an annealing temperature (col.4, lines 24-27). Lawecki et al. disclose that any process for forming a container that generates enough heat to render an article substantially free of contaminants can be applied in their invention. Therefore, it would have been obvious to one with an ordinary skill in the art at the time the invention was made to have modified the method of Lawecki et al. by having added a glass forming station for performing the steps of forming a glass syringe barrel, as taught by Logothetis, so that both glass and plastic syringes can utilize the same enclosure (10) of class 100 environment in the subsequent processes of producing a prefilled syringe.

Regarding claims 10 and 11, the exact temperature range of heating glass to a pliable state for shape forming and the temperature range of annealing depend on the type of glass and are known by those skilled in the art (applicants' specification page 19, lines 19-27). Therefore, the temperature range for heating the glass tube is considered to be about 760°C to 1100°C, and the temperature range for heating the glass tube to an annealing temperature is considered to be about 560°C.

14. Claims 7, 15 and 33 are alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Jurgens, Jr. et al. (US 4,628,969).

To the extent that applicants do not agree with the general disclosure of the lubricating and filling steps in the method disclosed by Lawecki et al., then Jurgens, Jr. et al. discloses a process for producing a prefilled plastic syringe having a cylindrical side wall, receiving end (28) and outlet nozzle (24), see figures 1 & 2 for example, including the steps of: coating a syringe barrel (22), a tip cap (26) and a stopper (30) with silicone solution (col.3, lines 10-16); applying the tip cap to close outlet nozzle (col.4, lines 16-17); filling the syringe barrel with a desired substance (col.4, lines 19-21) through the receiving end; then applying the stopper to the receiving end (col.4, lines 22-25). Therefore, it would have been obvious to an ordinary skilled person in the art at the time the invention was made to have modified the method of Lawecki et al. by having provided the steps of filling, as taught by Jurgens, Jr. et al., in order to fill the syringe through the receiving end.

15. Claim 37 is alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Smith et al. (US 5,597,530).

To the extent that applicant does not agree with the general disclosure of the lubricating and filling steps in Lawecki et al. method, then Smith et al. discloses a process for producing a prefilled plastic syringe having a cylindrical side wall (24), receiving end (22) and outlet nozzle (20), see figure 1 for example, including the steps of: inserting a stopper (16) into the syringe barrel (12) through the receiving end (col.5, lines 48-50); filling the syringe barrel with a desired substance through the outlet nozzle (col.6, lines 9-

11); then applying a tip cap (14) to the outlet nozzle (col.6, lines 20-21). Therefore, it would have been obvious to an ordinary skilled person in the art at the time the invention was made to have modified the method of Lawecki et al. by having provided the steps of filling, as taught by Smith et al., in order to fill the syringe through the outlet nozzle.

16. Claims 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

Lawecki et al. discloses a method of producing a prefillable glass syringe assemblies including the steps of: forming a glass syringe (126) in a glass forming device (col.3, lines 38-43), transferring the glass syringe to an enclosure (10) of class 100 environment (col.3, lines 5-10) without any cleaning or sterilization, cleaning the glass syringe by directing a stream of filtered air toward the glass syringe to keep contaminants from setting on the glass syringe (col.4, lines 22-24), lubricating the glass syringe (col.8, lines 19-25), transferring the glass syringes to a packaging station (58), placing the glass syringe in a holder (68) to form an array of eight glass syringes (col.7, lines 17-21), enclosing the array in a second container (128) (col.7 lines 25-28), which meet all of applicant claimed subject matter except for the detailed process of forming a glass syringe.

However, Logothetis discloses a process for forming a glass syringe assembly on automatic machinery (col.3, lines 40-43), wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (col.3, lines 57-62), see figs.1 & 2; the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (col.5, lines 8-14), see fig.5; the glass syringe

assembly is then heated to an annealing temperature (col.4, lines 24-27). And, Lawecki et al. discloses that any process for forming a container that generates enough heat to render an article substantially free of contaminants can be applied.

Therefore, it would have been obvious to an ordinary skilled in the art at the time the invention was made to have modified the method of Lawecki et al. by having provided a glass forming station for performing the steps of forming a glass syringe assembly, as taught by Logothetis, so that both glass and plastic syringes can utilize the same enclosure (10) of class 100 environment in the subsequent processes of producing a prefillable glass syringe assemblies.

Regarding claim 21, the range of the heating and annealing temperature are known by an ordinary skilled in the art depending on the type of glass (applicant's specification page 19, lines 19-27); therefore the heating temperature is considered to be about 760°C to 1100°C and the annealing temperature is considered to be at least 560°C.

Regarding claims 26-27, Lawecki et al. discloses a HEPA filter (50) including an independent blower (col.4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment. Lawecki et al. further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (col.4, lines 51-54).

Regarding claims 30-31, Lawecki et al. discloses a plastic molding device enclosed within the enclosure (10) (col.3, lines 25-31). Similarly, the modified method. by Logothetis, would have the glass forming device enclosed within the enclosure (10) of class 100 environment as well.

17. Claims 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Jurgens, Jr. et al. (US 4,628,969).

Lawecki et al. discloses a method of producing a filled syringe which meets all of applicant's claimed subject matter except for the step of sterilizing the prefilled syringe.

However, Jurgens, Jr. et al. discloses a method of producing prefilled sterile plastic syringes including the step of sterilizing a prefilled syringe (20) after the step of filling and the step of applying the stopper (30) and prior to the step of packaging the prefilled syringe (col.3, lines 33-43).

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified to method of Lawecki et al. by having provided the step of sterilizing the prefilled syringe, as taught by Jurgens, Jr. et al., in order to maintain the cleanliness and sterility of the syringe prior to packaging.

18. Claims 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Smith et al. (US 5,597,530).

Lawecki et al. discloses a method of producing a filled syringe which meets all of applicant's claimed subject matter except for the step of sterilizing the prefilled syringe.

However, Smith et al. discloses a method of producing prefilled sterile plastic syringes including the step of sterilizing a prefilled syringe (12) after the step of filling and the step of applying the tip cap (14) (col.6, lines 26-44) and prior to the step of packaging the prefilled syringe.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified to method of Lawecki et al. by

having provided the step of sterilizing the prefilled syringe, as taught by Smith et al., in order to maintain the cleanliness and sterility of the syringe prior to packaging.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 308-7769 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LH
June 17, 2002

Stephen F. Gerrity
Primary Examiner